Clinical Use of Sedative Agents During a Daily Sedation Awakening Trial

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Background

- More than 300,000 patients mechanically ventilated each year in Intensive Care Unit (ICU)
- Most of these patients receive intravenous (IV) sedation
Common sedation agents:
- Propofol (short-acting analgesic)
- Midazolam (a benzodiazepine)
- Fentanyl (an opioid analgesic)
- Combinations of above

Continuous IV sedation is associated with prolonged mechanical ventilation (Kollef et al, Chest 1998)
Background

- Daily sedation awakening trial (SAT) has become the standard for practice (Kress et al, NEJM 2000)
- SAT: continuous IV sedation decreased or stopped in an attempt to wake patient
Rationale

- There should be a relationship between the sedative agent given (type, dose, duration of administration) and the pharmacodynamic response observed in a patient.
Study Objective

- To identify the relationship between sedation agent administration, patient wake-up time and subsequent sedation agent status following a daily SAT
Study Design

- Multicenter trial: Partnership for Excellence in Critical Care (PECC)
- University of MN: Center for Excellence in Critical Care Medicine
- MICU at UMMC Fairview Hospital
- 12 week prospective trial
- Data collection will be complete August 20
Inclusion Criteria

- MICU patient
- Mechanically ventilated
- Continuous IV sedation
Exclusion Criteria

- Tracheostomy
- Failed safety screen:
  - Central nervous system complications
  - Neuromuscular blockade medications
  - Unstable airway
  - FiO₂ > 70%
  - High frequency ventilation
  - MD cancels
Summary of Protocol

- Patient screened for qualification
- Sedation decreased or stopped
- Data recorded on collection sheet
# Data Collection Sheet

## Sedation Awakening Data

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Safety Test (circle)</th>
<th>Safety Fail Reasons (Circle all that apply)</th>
<th>Sedation Meds (Circle received in past 6 h.)</th>
<th>Start Arousal Score (1-6)</th>
<th>Start wake up Stop wake up</th>
<th>End Arousal Score (1-6)</th>
<th>Outcome after dose reduction (Circle first event that occurred)</th>
<th>Exit Reasons</th>
<th>Final med status (circle one)</th>
<th>Adverse Events</th>
<th>NOTES (clarify if circled &quot;word&quot;)</th>
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</thead>
<tbody>
<tr>
<td>Pass</td>
<td>Fall</td>
<td>CNS NMB ARVY PICO MD&quot;</td>
<td>None Dilaudid Micazolam Fentanyl Lorazepam Propofol Morphine Dex Haloperidol</td>
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Start wake up is time of sedation stop or decrease.
Stop wake up is time patient wakes up and follows command OR awakening is exited for exit reason or adverse event.
MSAT Arousal Scale

1. Eyes stay closed and no patient movement is observed in response to stimulation.
2. Eyes stay closed, but other patient movement observed in response to stimulation.
3. Eyes closed but open to shoulder shake plus sound of voice.
4. Eyes closed but open to sound of voice.
5. Eyes open spontaneously but not tracking.
6. Eyes open spontaneously with tracking.
Additional data collection

- APACHE II score (a severity of illness score)
- Drug dosing 4 hours prior to SAT
- Liver and renal function
Results at week 11

- 25 patients (12 male, 13 female)
- 41 sedation awakening trials
- Mean age 53±13 years
- Mean APACHE II Score 21±6
- Interpretation of the Apache Score 20-24: ~40% risk of death
- Actual mortality rate 16%
Results

- Sedation regimens:
  - propofol (43%)
  - fentanyl (20%)
  - fentanyl and midazolam (20%)
  - midazolam (10%)
  - fentanyl and propofol (7%)
Results

- Awake at start of SAT: 18 trials (44%)
- Did not wake up: 5 trials (12%)
- Median time to follow command in remaining 18 trials: 90 minutes
Results

- Sedation stopped following SAT: 22 trials
- Sedation decreased to ≤50% original dose: 8 trials
- Patients extubated following SAT: 7
Conclusions

- Propofol is the most common sedating agent used in UMMC Fairview MICU for patients undergoing SAT
- Nearly half of patients are awake before SAT is begun
- Patients who receive a SAT are likely to stop or reduce the dose of sedation agents
Thank you

- AHC Predoctoral Fellows Clinical Research Program
- Henry Mann, PharmD
- Craig Weinert, MD
- Monica Lupei, MD
- Robin Bushinski, RN
- Paula Aherns, RT
Questions?